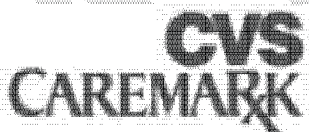


# PSJ3

## Exhibit 578

*CONFIDENTIAL AND PRIVILEGED ATTORNEY CLIENT DOCUMENT*

# **EVALUATION OF SUSPICIOUS ORDERS MONITORING SYSTEM FOR**



*BY*

**THE Drug & Chemical**  
ADVISORY GROUP, LLC

April 6, 2012

*CONFIDENTIAL and PROPRIETARY*

## A. EXECUTIVE SUMMARY

On March 26-28, 2012, Terrance W. Woodworth, Partner, The Drug and Chemical Advisory Group, LLC. (DCAG) met with key CVS Caremark (CVS) Logistics Loss Prevention and Distribution Center officials and performed an assessment of the suspicious orders monitoring (SOM) program for controlled substances in Schedules 3 - 5 and the List I chemicals ephedrine and pseudoephedrine. A comprehensive explanation of DCAG findings and recommendations is detailed below; however, there are several actions that DCAG suggests CVS take in the near future:

- Remove the terminology 'suspicious' orders in most places in corporate documentation and replace it with the alternate term 'irregular' orders which more accurately reflects the status of a controlled substance or listed chemical order under review
- Complete the revision and finalize the CVS "List I Chemicals and Control Drug Policy and Procedure" for the SOM Program which includes specific responsibilities, procedures and actions for further review of an order, as well as procedures for reporting suspicious orders to DEA
- In the near term, continue the re-examination and modification of the current 'irregular' order algorithm, its parameters, and calculations used to compute thresholds for customer orders and the placement of orders above thresholds (irregular orders) on the daily Inventory (Item) Review Report (IRR)
- Enhance the quantitative criteria and continue developing additional qualitative criteria for determining whether an order is suspicious, and consider setting separate parameters or weightings for the scheduled listed chemicals ephedrine and pseudoephedrine
- Continue to elevate the visibility and importance of the SOM program throughout the company
- Facilitate greater collaboration and exchange of information among the different corporate elements that have

responsibilities for controlled substance and listed chemical activities, i.e. Operations, Retail, Logistics and Distribution Centers, in an effort to address the compartmentalization of actionable controlled substance and listed chemical information

## B. BACKGROUND

With its headquarters in Woonsocket, Rhode Island, CVS Pharmacy, Inc. and its subsidiaries and affiliates including Caremark Rx, LLC. (CVS Caremark) (CVS) is the largest health care provider in the United States. CVS operates nineteen (19) distribution centers, eleven (11) of which handle controlled substances, and supplies its more than 7,300 retail stores. The eleven distribution centers that handle Schedule 3, 3N (non-narcotic), 4, and 5 controlled substances and distribute these controlled products to CVS stores throughout the country are all fully registered with the Drug Enforcement Administration (DEA) and the appropriate state agencies as distributors.

All individual CVS stores that handle controlled substances in any manner are also registered separately with DEA and the appropriate state agencies as pharmacies. A separate CVS retail system continuously ensures the DEA registration for each store is current and valid for all schedules of controlled substances. This registration information verification is a separate and additional requirement for distributors under the regulations (21 CFR 1301.74 (a)) and CVS has integrated these registration verifications into its retail system. In addition to controlled drug products, the eleven distribution centers also handle and ship the List I chemicals ephedrine and pseudoephedrine in non-prescription drug products (scheduled listed chemical products) and are properly registered with DEA and the relevant state agency for these activities. All of these substances are subject to the regulatory controls set forth in the Controlled Substances Act.

The Controlled Substances Act (CSA) and its implementing regulations require that CVS design and operate a system to disclose suspicious orders of controlled substances and listed chemicals. CVS is also required to inform the nearest DEA Field Division Office in the area of the registrant of any suspicious orders of controlled substances or listed chemicals when discovered. For controlled drugs, these include

orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency (21 CFR 1301.74 (b)). For scheduled listed chemical products, these include an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that may indicate the listed chemical will be used in violation of the CSA (21 CFR 1310.05 (a)(1)). The suspicious order reporting requirements exist to provide DEA with pertinent information about potential improper or illegal activity in an expeditious manner. CVS has designed and operates a system to disclose suspicious orders of controlled substances and listed chemicals and continues to refine and improve its system.

As part of CVS's efforts to continuously assess and enhance its controlled substances and listed chemical systems and processes, it has requested the assistance of the Drug and Chemical Advisory Group, LLC. (DCAG) in conducting an evaluation of its suspicious order monitoring (SOM) program for controlled substances in Schedules 3, 3N, 4, and 5 and the scheduled listed chemical products ephedrine and pseudoephedrine. CVS's SOM is operated centrally from the Knoxville, Tennessee distribution center (DC).

On March 26 - 28, 2012, DCAG Partner Terrance W. Woodworth met with several key members of the CVS SOM team: Frank R. Devlin, Director Logistics Loss Prevention (Rhode Island), John Mortelliti, Logistics Regional Director, Loss Prevention (New Jersey), Pamela J. Hinkle, Senior Loss Prevention Manager, (Tennessee), Paul Lawson, Logistics Loss Prevention Analyst (Tennessee), Aaron J. Burtner, Logistics Loss Prevention Analyst (Indiana), Attorney Margaret P. Griffiths, (Illinois), and King & Spaulding Attorney Stephen P. Cummings (Georgia). The discussions and document examination and revision during this three day period centered on the current processes for reviewing, analyzing and detecting suspicious orders for controlled substances and listed chemicals placed by individual CVS stores to any of the eleven CVS distribution centers which handle controlled substances and listed chemicals. Additionally, Ms. Hinkle provided the participants a tour of the CVS Knoxville, Tennessee distribution facility and a general description of the flow of controlled product and listed chemical receiving, storage, order filling, shipping and handling. Ms. Hinkle also arranged for a brief visit to CVS store #5639 to observe the pharmacy operations.

## C. SUSPICIOUS ORDERS MONITORING (SOM) PROGRAM

The CVS suspicious orders monitoring (SOM) program for Schedule 3 - 5 controlled substances and the scheduled listed chemical products ephedrine and pseudoephedrine is a comprehensive system led by a multidisciplinary team and includes several key components: an SOM policy and procedure document, an automated algorithm for identifying irregular orders, an irregular order work instruction and flow map, a two person specialized logistics analysis team, additional supporting analytical tools and reports, and a centralized operational function. These components are discussed separately below.

### SOM Policy and Procedure

The overarching policy and guidance for the CVS SOM is set forth in the CVS "List I Chemicals and Control Drug Policy and Procedure" document. This document sets forth the CVS policy concerning suspicious orders of controlled substances and listed chemicals and underscores that when CVS determines any order to be suspicious, it directs that the order will be stopped, not shipped and reported as soon as possible to DEA. The policy document distinguishes between irregular orders and suspicious orders. Irregular orders for controlled substances or listed chemicals may meet or exceed some of the alert criteria established by CVS as early warning indicators of situations necessitating further analysis; and in many cases CVS places a hold or freeze on an irregular order until the irregularity is resolved to the satisfaction of senior logistics loss prevention officials. The SOM policy establishes procedures for handling and analyzing irregular orders, steps for further investigation, escalation of review of certain orders and situations, and procedures for notifying DEA when an order is determined to be suspicious. The CVS SOM program is much broader than its core algorithm and is augmented by manual reviews and analyses, and complemented further by special analytical tools using multiple databases and sources of information.

### Automated Algorithm

The use of electronic systems with automated algorithms and programmed calculations for identifying orders for further review is essential in the industry in consideration of the volume of orders, inventory control methodology and short cycle times. These systems

are common throughout the pharmaceutical industry and are also acceptable to DEA. CVS has developed a complex automated algorithm with eight attributes and assigned model weights per attribute. The algorithm was designed to identify orders exceeding certain quantity limits based on order history for a given CVS store, a possible increasing trend of ordering and orders placed on a frequent basis. Orders from any of the more than 7,300 CVS stores that exceed established parameters are flagged as irregular orders on a daily basis and listed on a special report entitled "Item Review Report (IRR) - Control Drugs" for further review and assessment. If any item on an order is flagged as irregular by the CVS algorithm, the entire order is placed on the daily IRR.

### Irregular Order Work Instruction

CVS has also created a very thorough set of instructions for reviewing all possible irregular orders. At various times during the review process, an irregular order may be determined to be a valid order, or the order may require several additional levels of analytical review, or the order may be established as suspicious. The work instruction includes detailed steps for the review at each stage in the process. The work instruction also includes points during the process for when and how the reviewing Analyst should notify the distribution centers about the status of orders under review. The work instruction also details the various databases, additional analytical tools and methods the Analyst should explore to gather greater intelligence concerning the irregular orders. The entire SOM irregular order item review and analysis system is also depicted in a detailed Flow Map.

### Specialized Logistics Analysis Team

The CVS SOM program is comprised of a team of managers, distribution center personnel, attorney advisors, and two specialized logistics analysts operating on a national basis under the auspices of the Logistics Loss Prevention Director and the Logistics Regional Director, Loss Prevention. The SOM team can draw upon any other CVS resource throughout the United States for assistance in gathering information or obtaining further detail about an irregular order or its circumstances. One Analyst is very experienced in the SOM program and the other is rapidly gaining this knowledge, and both are specialized in the field of controlled substances and listed chemicals.



The two SOM Logistics Analysts are critical thinkers and fully understand the importance of their functions and responsibilities.

Every day the Logistics Analysts are provided with a several hundred page report of irregular orders generated by the CVS SOM automated algorithm which is being applied against all orders placed with the CVS distribution centers by any CVS store in the country in the last twenty four (24) hours. The Logistics Analysts are responsible for initiating, tracking and documenting the steps in the critical review and related analyses of all irregular orders. The Logistics Analysts are also responsible for gathering additional information at various stages during the process, including contacting the Pharmacist In Charge at the individual CVS store concerning an irregular order. In this regard, the SOM team has created "Store Environment Speaking Points" for controlled drugs, as well as listed chemicals and these documents serve as a template to guide the inquiry with store personnel. The Logistics Analysts are also responsible for contacting the Regional Loss Prevention Manager or Senior Loss Prevention Manager, as appropriate, to discuss or forward the results of the irregular order review. In some cases it will be necessary for certain irregular orders to be subjected to more extensive investigation and the field loss prevention personnel may aid in the further review.

The Logistics Analysts document all reviews on the review report spreadsheet and maintain files of this documentation at their location. The Logistics Analyst also signs and dates each daily IRR on the date it is received. Additionally, the daily Item Review Report is generated at each of the eleven key distribution centers, and each relevant distribution center also receives copies by email of the information and findings concerning the review conducted by the Logistics Analysts and/or other CVS personnel of an irregular order for their records, all of which are maintained for a three year period. These additional record keeping steps appear to satisfy a possible DEA concern for each CVS distributor registrant to request permission for a central record keeping permit related to the CVS SOM program.

Beyond the regular, in-depth daily review and analysis of irregular orders, the SOM team led by the Logistics Analysts is actively searching for any peculiar or unusual activities, patterns or clues which may indicate possible controlled substance irregularities which require further investigation and development by the SOM team and other CVS elements.



## Supporting Analytical Tools and Reports

CVS maintains many separate databases, both internally and externally, containing controlled substance and listed chemical data and information which can be accessed by the SOM team members. The SOM team determines and ensures implementation of the additional analytical tools and specialized reports that are needed regularly to support their function and responsibility. These additional databases, analytical tools and specialized reports are valuable and integral parts of the SOM review and analysis effort. Presently, the SOM Logistics Analysts are regularly using the business intelligence software Infopak, Viper, and Microstrategy to augment the information related to an irregular order. These systems and programs include such additional analytical and comparative data as a correlation of quantity ordered by ingredient per store compared with the quantity dispensed over a given time period, any prescription activity reflecting common doctors or common patients for a given product over a specific time period, as well as a comparison of the method of payment (i.e., cash, insurance, drug cards).

The SOM team has also embarked on producing several Top Ten Project reports nationally, i.e., by drug, by stores, by prescriber, and by distribution center; and the team has initiated a rolling four month snap shot of all controlled substances and listed chemical activity nationwide (currently for November 2011 through February 2012) and this will continue to be rolled over and provided to the SOM team every month.

## Centralized Operational Function

On behalf of CVS Pharmacy, Inc. and its subsidiaries and affiliates, the SOM program is operated centrally from the Knoxville, Tennessee distribution center and includes the review and analysis of all orders for controlled substances in Schedule 3 - 5 and List I chemicals that are placed with one of the eleven CVS distribution centers by any CVS store nationwide. CVS does not distribute any controlled substances or listed chemicals to an external entity. The centralized SOM operation includes several advantages for detecting and preventing possible improper activities involving controlled substances and/or listed chemicals.

The various CVS subsidiaries and affiliates are very closely interrelated, particularly with regard to the activities involving Schedule 3 - 5 controlled substances and/or the List I chemicals. With a few exceptions, the corporate supply chain, for example, is almost a completely closed system of distribution. The extensive corporate system of databases, specialized information technology programs and capabilities for customized data queries from wholesale receipt, through the corporate distribution system, to the individual CVS pharmacy, including prescriber and patient data, are transparent and accessible to the SOM Logistics Analysts. This almost complete system visibility affords specialized data and information collation and analyses not available to most other organizations.

Even within the CVS system, the centralized SOM operation is further capable of collating select distribution center data, information and related trends and yielding identification, for example, of common controlled substance activity sourced from multiple distribution centers. Additionally, the data gathering, collation and examination by the centralized SOM operation provides a more complete view of a given activity which may overlap different distribution centers or different CVS pharmacy stores. These unique capabilities of the centralized SOM operation enable or alert CVS to possible issues of concern, unusual activities or trends that can be evaluated further to determine appropriate action.

The centralized SOM operation is also an expeditious means of examining irregular orders for all CVS distribution centers nationally, gathering further data for analysis and decision making. Additionally, the continuous centralized SOM operation and regular contact by the two Logistics Analysts will become institutionalized and the various corporate entities, i.e., the distribution centers, the Pharmacists In Charge, and the field Loss Prevention personnel are likely to become more interactive and instrumental in resolving controlled substances and listed chemical issues.

#### D. ONGOING IMPROVEMENTS OF THE SOM PROGRAM

CVS is regularly evaluating the operation of its SOM program and has identified several areas where improvements and enhancements are necessary and have been initiated. For example, CVS has updated the SOM policy documents and the related work instructions and supporting tools. CVS has also expanded and attempted to

institutionalize the critical analyses of orders for controlled substances and listed chemicals and the associated activities. CVS has conducted further examination of its irregular order algorithm and determined that changes are necessary to provide greater accuracy in establishing irregular orders prior to further analysis. This ongoing assessment with specifically identified tasks and milestones has been formalized as the "IRR SOM Review Project Plan".

## Irregular Order Algorithm

CVS has embarked on a major effort to enhance the sophistication of its irregular order algorithm and subsequent analytical efforts. In addition to CVS's internal re-examination of the algorithm and its results, two external vendors have been contacted and provided with possible modification requirements for the algorithm. CVS is pursuing a two pronged strategy to enhance its irregular order algorithm: a near term effort to adjust the precision of the current algorithm and a longer term effort which may involve the complete redevelopment of an irregular order algorithm(s). One external vendor, Analysis Group, Inc. (AGI) in the Boston, Massachusetts area is a long term CVS associate. AGI maintains extensive data for the retail operations of CVS and use of this additional data would significantly enhance CVS's irregular order analyses capabilities. The other external vendor is E-SupplyLink located in Traverse City, Michigan. E-SupplyLink offers supply chain management and electronic data interchange with specialized suspicious order monitoring systems. CVS has interacted with E-SupplyLink concerning SOM initiatives and is currently examining next steps.

## Considerations for Analysis Group, Inc. (AGI)

DCAG recommends CVS consider requesting that AGI undertake the following actions regarding the enhancement of the irregular order algorithm:

- Fully analyze the trends, characteristics and indicators from the data associated with the controlled substance activities of CVS Store #219 and Store #5195 and recommend methods and adjustments to the algorithm parameters that would more accurately detect and provide early warning of periodic increases in order frequency and slow or gradual volume increases;

- Provide recommendations concerning adjustments or changes in the irregular order algorithm that would preclude the current limitations and distortion of early warning indicators of change in order frequency, in gradual volume increases, as well as in related trend analyses, particularly from baseline high volume situations;
- The existing algorithm measures or compares an active ingredient ordered by a given store against the store's own past order history. Provide recommendations concerning the addition of criteria to compare/measure an order for a given ingredient against the class of like ingredients, i.e., 'alprazolam' and the class of all 'benzodiazepines';
- Provide recommendations regarding the addition of a dimension to the algorithm to compare/measure a given store's order activity of an ingredient against orders for this ingredient by like size or volume stores, nationwide, and by distribution center;
- Provide recommendations to expand the scope of high risk data by adding a dimension to capture the ordering combination or mixture of hydrocodone + alprazolam + carisoprodol; and also identify high volume or high frequency ordering of two or more of these ingredients (the combination/mixture of these substances is a well known 'cocktail' of substances taken by drug abusing individuals);
- Examine the algorithm parameters and adjust for large percentage increases by active ingredient which are not significant from a practical sense, i.e. an increase from one bottle to two bottles;
- Examine the order history for the past two or three years for the ingredients pseudoephedrine and ephedrine, and recommend possible new thresholds or a new irregular order algorithm only for these two ingredients.

DCAG also recommends that CVS Information Systems (IS), the SOM team and AGI consider creating special reports to aid the irregular order analyses performed by the Logistics Analysts, such as:

- What store had the highest volume for each of the following ingredients: hydrocodone, alprazolam, carisoprodol, buprenorphine, and phentermine in the past month?
- What active drug ingredient had the highest volume in the past month, nationally? by state? and by distribution center?
- Which ten stores are the top hydrocodone purchasers over the past six months? What are the outlying stores beyond all others?
- Over a six month period, what is the percentage of the controlled drug hydrocodone versus all non-controlled drugs by store? and by month? and the percentage of hydrocodone versus all Schedule 3 - 5 controlled drugs by store? and by month? Identify any store whose controlled drug prescription activity represents more than 40 percent of all prescription (controlled and non-controlled substance activity) for that store;
- Examine the CVS order history for the past two years for Schedule 3 - 5 controlled substances and List I chemicals (ephedrine and pseudoephedrine) and determine the average shipment quantity nationally per individual drug ingredient, the average per state by drug ingredient, and by distribution center;
- Identify any prescriber whose prescriptions for controlled substances are filled by more than ten CVS stores, and after review and further analysis by the Logistics Analyst adjust the report parameters based on the size of the report;
- Enable the creation of a rolling Item Review Report (IRR) for irregular orders for each week rather than only at the beginning and end of each month (this will lessen the daily volume of irregular orders that must be examined by the Logistics Analysts);
- Once an order item on the IRR has been examined by the Logistics Analysts and cleared for filling/shipment, remove it from future IRR reports

## E. RECOMMENDATIONS

CVS Pharmacy, Inc. has established an effective, centrally operated suspicious orders monitoring program for its eleven distribution centers for all Schedule 3, 3N, 4, and 5 controlled substances and the scheduled listed chemicals ephedrine and pseudoephedrine, and CVS continues to update and improve its SOM program. As brief background, in approximately the past six years DEA has heightened its efforts concerning suspicious orders for controlled substances and listed chemicals. In this regard, CVS has received two letters from DEA setting forth the requirements in the law and regulations concerning a registrant's responsibilities to maintain effective controls to prevent diversion and to report to DEA suspicious orders of controlled substances. These letters are generic, form letters; however, they were sent by DEA to all registered manufacturers and distributors as part of DEA's "Distributor Initiative" and as a means of documenting its concerns and providing official notice to DEA registrants. It is also important to note that the regulations establish the **minimum** requirements necessary to comply with the law.

In an effort to assist CVS in enhancing its SOM program, The Drug and Chemical Advisory Group recommends several actions which are explained below:

1. It is recommended that the terminology in most corporate documentation be changed from 'suspicious' to 'irregular' orders, except in the cases where an order is actually determined to be suspicious and thus requires reporting to DEA. This connotation would correspond with CVS's tiered system wherein orders which meet certain established criteria are flagged as irregular orders and subjected to further review and held, as appropriate, until resolution and final action. Additionally, it is recommended the term 'unusual' frequency found on the IRR header page under Description of the Attribute "BinaryDay" be changed to frequency 'of concern' because the irregular order has not been determined to be suspicious, at the time the daily IRR is generated.
2. Complete the revision and finalize the "List I Chemicals and Control Drug Policy and Procedure" for the SOM program which includes specific responsibilities, procedures and actions for further review of an order, as well as procedures for reporting suspicious orders to DEA. This policy makes it clear that when an



order is determined to be suspicious, it is stopped and not shipped and reported expeditiously to DEA.

3. CVS is re-evaluating its irregular order algorithm and DCAG has made a number of recommendations and suggestions in the section above concerning the algorithm. However, it is important to note that the complexity or sophistication of the algorithm and its calculations are secondary to the meaning and usefulness in highlighting orders that may require further review. If a threshold is established for a given store or drug ingredient and it proves not to be effective in accomplishing the intended purpose, it should be revised and then closely monitored. When long term, well established store ordering patterns, frequencies, and quantities are known or identifiable, thresholds can be set accordingly, unless or until circumstances change. It may be instructive to divide stores into defined groupings (i.e., size, activity, similar characteristics) and intentionally establish thresholds at stricter levels on a temporary basis for purposes of establishing a baseline of ordering activity. It may also be effective to have more than one algorithm or apply different weightings and/or calculations to different the drug ingredients or products, i.e., the listed chemical products ephedrine and pseudoephedrine versus controlled drugs. In any event, it is essential that one or more of the SOM team members be part of the discussions and further evaluation/development of the algorithm and calculation(s) and setting of thresholds.
4. It is recommended that CVS continue elevating the visibility and importance of complying with the SOM program throughout the corporation, noting the exposure vulnerabilities and possible consequences of system weaknesses and failures, acknowledging that a valid and reliable SOM system is not static and requires continuous adjustment and fine-tuning. Provide greater structure and input to the SOM program by fully integrating the relevant corporate functions, data and experiences, even on an ad hoc or part-time basis, to facilitate access to more detailed, necessary and real-time information for assessing irregular orders for controlled substances and listed chemicals. It is further recommended that the extensive institutional knowledge and experience of these different corporate elements pertaining to controlled substances and listed chemicals activities of CVS stores and ordering patterns be documented to the extent possible and



shared through various team meetings, training sessions and corporate conferences. CVS may also consider requiring a Standard Operating Procedure (SOP) for Retail Operations to support the CVS SOM program.

5. It is recommended that the Loss Prevention Analysts continue to document their methodologies in analyzing irregular orders, and attempt to automate this methodology and possibly include it as part of the irregular order algorithm or as an additional automated step in the analysis. It is further recommended that the Logistics Analysts and other knowledgeable CVS personnel build out the possible scenarios relating to irregular orders for controlled substances and listed chemicals and the different, feasible explanations for increased order quantities or frequencies, and attempt to automate these scenarios as well.
6. It is recommended that CVS develop and document the circumstances or situations when it would be prudent for an irregular order, while not reaching the level of suspicious, to be reported to DEA, for both controlled drugs and for scheduled listed chemical products.
7. It is recommended that the eleven distribution centers be provided detailed guidance for responding to DEA inquiries, as well as DEA on-site visits involving the CVS SOM program, how it functions, and its central location and that central record keeping permission is not required because copies of the records required to be kept by law and regulation are all maintained at these registrant locations. It is also recommended that the procedure for sending the distribution centers copies by email of all documentation associated with irregular order reviews and any related inquiries by Logistics Analysts and other Loss Prevention personnel be institutionalized.
8. It is recommended that the controlled substances activities for all CVS stores in the State of Georgia be added to the list of priorities for the CVS SOM program initiatives.
9. The CVS RxAim system apparently has the capability to automatically increase the target inventory levels (TILs) at individual stores for any product including controlled substances. The SOM team and Logistics Analysts are generally not aware of

these increases, and periodic store contact has revealed some controlled drug items were not needed by the store. It is recommended that the methodology for automatic increases in store TILs be evaluated with regard to controlled substances and listed chemicals. If CVS determines to continue this practice, it is recommended that the SOM team be provided this information either in advance or concurrently for use in assessing any irregular orders.

10. Individual CVS stores have the capability to place orders for controlled drugs outside of the normal CVS distribution center network, i.e., Cardinal Health or McKesson, for many different and valid reasons. However, these purchases are not included in the SOM system, its algorithm or calculations, or subsequent review and analysis of irregular orders. The outside vendor purchase information is available after the transaction has been completed through use of different CVS systems. These transactions limit the effectiveness of the SOM program in identifying irregular or suspicious orders and trends. It is recommended that CVS re-evaluate its outside vendor purchase policy for controlled substances and listed chemicals, and at a minimum, institute special separate reports of these outside controlled drug purchases for further review and analysis by the SOM team. The outside vendor purchases also subject those individual CVS store orders to evaluation by the SOM programs of the external vendors and possible reporting to DEA.
11. CVS regularly generates and submits reports for its eleven distribution centers for all transactions involving Schedule 3 narcotic substances, i.e., hydrocodone products, to DEA's Automated Reports and Consolidated Orders System (ARCOS), and this information may be useful to the Logistics Analysts in their review of trends for these substances, as well as trends per store or distribution center. Additionally, the ARCOS reports could assist in obtaining and/or verifying previous store purchasing patterns for these narcotic substances, as well as determining any cumulative purchases under review.
12. It is recommended that the SOM team continue to keep abreast of DEA and State agency controlled substances activities and remedial actions, monitor the appropriate federal and state agency websites, and be alert to controlled substances issues or

problems involving products and/or CVS locations in an effort to continually improve the CVS SOM system. The various DEA documents related the National Forensic Laboratory Information System (NFLIS) are also very useful in identifying what drugs and substances are priorities for drug law enforcement agencies throughout the country based on actual law enforcement laboratory drug exhibits analyzed (attached as Attachment # 1).

13. In DCAG's review of the CVS SOM program, it was apparent that the overall approach is not focused on reviewing and rapidly releasing an order to ensure store delivery dates. The priority clearly is to detect any problem or issue that indicates an order may not be valid or legitimate. The review and analysis of irregular orders are completed expeditiously; and while sales productivity, customer store and patient satisfaction are paramount, the foundation of the CVS SOM is ensuring the legitimacy of these transactions.

## ATTACHMENT 1

National Forensic Laboratory Information System (NFLIS) Report for 2010

### F. Contact Information

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